APR 2 0 2001

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K 010969

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
Stryker LEIBINGER® NEURO N100 RF Generator

General Information

Proprietary Name	NEURO N100 Radiofrequency Generator System
Common Name:	NEURO N100 RF Generator Generator, Lesion, Radiofrequency Neuro Clip Implant Applicator/Pistol Orthopedic manual surgical instrument 21 CFR 888.4540, Class I exempt
Proposed Regulatory Class:	Class II
Device Classification:	84 GXD
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Contract Manufacturer's Reg. #	8010177
Manufacturer's Registration #:	Pending
Contact Person:	Robin L. Rowe Regulatory Affairs Associate Telephone: 616-323-7700 x3295 Fax: 616-324-5412
Summary Preparation Date:	March 27, 2001

Intended Use

The subject device, NEURO N100 radiofrequency generator and accessory cables are indicated for use in neuro-surgical procedures. Its purpose is to show these signals on a color display, so that the surgeon can decide whether these signals show normal working neurological tissue or pathological tissue. These signals or at least parts of it can be stored to the hard disk to protocol the treatment. This technique is an important point, because the image technologies don't allow differentiating between different tissues in the brain. It allows the use of five recording channels simultaneously. The intended use for the NEURO N100 radiofrequency generator has not changed from the NEURO N50 LESION GENERATOR (K896450 cleared by the FDA 03/19/1991).

Device Description

The NEURO N100 RF Generator system consists of a radiofrequency generator and accessories intended for coagulation applications. Its purpose is to generate RF energy for delivery to a neurological tissue via a RF electrode over a specified time period (generally 60-90 seconds). The thermal energy at the site of application produces a lesion in the tissue. The NEURO N100 RF generator is used in unipolar and bipolar mode, and includes functions for controlling temperature at the distal end of the neurological electrode as well as for monitoring impedance and neurological signals. Coagulation parameters, such as power, impedance, voltage, current and temperature, can be recorded and displayed.

The NEURO N100 consists of a recording unit which is an additional designed to measure and record cell signals of neurological tissue, e.g. in the brain and support most of the known electrophysiological localization principles. The whole system consists of the NEURO N100 device, a transmitter box, an audio/trigger box, a preamplifier box, cables and accessories. The NEURO N100 is totally PC based, which means, that it implements a standard PC system.

Substantial Equivalence

EQUIVALENT PRODUCTS:

The NEURO N100 is substantially equivalent to already legally marketed devices in commercial distribution. Examples of these devices is listed below and additional literature is included in Appendix F.

NEURO N50– Submitted by the former Leibinger & Fischer Ltd. (refer to, Administrative Information, Submission Purpose for Stryker Leibinger acquisition of product lines).

Robin L. Rowe
Regulatory Affairs Representative
March 27, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2001

Ms. Robin L. Rowe
Regulatory Affairs Associate
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K010969
Trade/Device Name: NEURO N100 Radiofrequency Generator System
Regulation Number: 882.4400
Regulatory Class: II
Product Code: GXD
Dated: March 30, 2001
Received: April 2, 2001

Dear Ms. Rowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010969

Device Name: NEURO N100 Radiofrequency Generator System

Indication For Use:

The NEURO N100 Radiofrequency Generator System

The subject device, NEURO N100 radiofrequency generator and accessory cables are indicated for use in neurosurgical procedures. Its purpose is to show these signals on a color display, so that the surgeon can decide whether these signals show normal working neurological tissue or pathological tissue. These signals or at least parts of it can be stored to the hard disk to protocol the treatment. This technique is an important point, because the image technologies don't allow differentiating between different tissues in the brain. It allows the use of five recording channels simultaneously. The intended use for the NEURO N100 radiofrequency generator has not changed from the NEURO N50 LESION GENERATOR (K896450 cleared by the FDA 03/19/1991).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH,Office of device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010969

Prescription Use ✓ or Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)